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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,688	03/26/2004	Katsuhiko Yanagihara	31978-201641	8599
26694	7590	10/04/2006	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/809,688

Applicant(s)

YANAGIHARA ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/11/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The applicant's response filed 7/20/06 to the Office action has been entered. Claims 1-36 are pending.

#### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-31 in the reply filed on 7/20/06 is acknowledged. The traversal is on the ground(s) that the Examiner has not even alleged that an undue searching burden would be required in examining the full scope of the claims. This is not found persuasive because as indicated in the Office action mailed 6/20/06, these inventions are independent or distinct have acquired a separate status in the art because of their recognized divergent subject matter. It is an undue searching burden in examining the full scope of the claims.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 32-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/20/06.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-11, 13-18, 20-21, and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagihara et al. (PNAS, 2002, Vol. 99(17), pg. 11317-11321).

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Yanagihara et al. disclose a single mismatch, which could be detected as a referred target of Mu transposition in the presence of 300,000-fold excess of non-mismatched sites (See pg. 11317, the Abstract). A 75nM target DNA is amplified by PCR (See pg. 11317, column 2, the first paragraph). The target DNA is contacted with Mu end DNA and Mu transposase under conditions for the Mu end DNA to transpose into the target at about the site of a mismatch, if the target comprises a mismatch, detecting transposition of the Mu-end nucleic acid into the target (See pg. 11319, fig. 1). Mu end DNA is detectably labeled (See pg. 11317, column 1, second paragraph). The method also uses control duplex nucleic acid as indicated by 76-bp DNA without a mismatch used as a target (See pg. 11318, column 2, second paragraph) comparable to the test double stranded nucleic acid target (See pg. 11320, column 1, first paragraph). The product of the transposition reaction is electrophoretically separated by size (See pg. 11318, fig.1). The mismatch indicates the presence of a mutation or a polymorphism (See pg. 11320, column 1, the first paragraph). The location of the mismatch is determined by the steps recited in claim 13 (See pg. 11319, column 2 and fig. 4). The nucleic acid of interest comprises a mutation in a CFTR (See pg. 11317, column 2, first paragraph). Unknown mutations are also detected (See pg. 11320, column 1, second paragraph). The Mu end sequence can be use as a primer site for PCR amplification of transposon-tagged DNA and another primer is specific to each subregion of interest (See pg. 11320, column 2, third paragraph).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagihara et al. (PNAS, 2002, Vol. 99(17), pg. 11317-11321), in view of Lampe et al. (6,368,830, issued April. 9, 2002).

The teachings of Yanagihara et al. are set forth in section 4 above. Yanagihara et al. do not disclose determining the amount of transposition products.

Lampe et al. disclose an isolated hyperactive mutant of Himar1 transposase that enhances overall transposition from 4 to 50 fold as measured in *E. coli* assay (See the Abstract). The transposase is used for identifying essential genes (See column 16, lines 40-60). The transposition product is easily quantified with labeled products (See column 7, lines 5-9).

One of ordinary skill in the art would have been motivated to apply labeled transposition products as taught by Lampe et al. because the labeled transposition is easily quantified. It would have been prima facie obvious to determine the amount of the transposition products.

7. Claims 12, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagihara et al. (PNAS, 2002, Vol. 99(17), pg. 11317-11321), as applied to claims 1-11, 13-18,

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20-21, and 23-27 above, and further in view of Jones et al. (2005/0037011, issued Feb. 17, 2005).

The teachings of Yanagihara et al. are set forth in section 4 above. Yanagihara et al. do not disclose the method, which is a high throughput method, screening an embryo mutation and tumor promoting mutation.

Jones et al. disclose the method of detecting Wnt5a gene (See pg. 10, [0098]). The mutated Wnt-encoding gene found in embryo leads to specific developmental defects (See pg. 1, [0003]). Automated method can be used to determine whether there is a mutation (See pg. 10, [0102]). Wnt5a serves as a tumor suppressor in a certain type of cancer (See 9, [0084]).

One of ordinary skill in the art would have been motivated to apply the automated method to detect mutation in embryo or tumor because as indicated by Jones et al. the mutation can be determined by automated method, which facilitates the procedure. It would have been prima facie obvious to apply an automated method to detect mutation in embryo or tumor promoting mutation.

#### Summary

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung *J. Tung*  
September 25, 2006

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

9/27/06